Exhibit A

State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.

Exhibit to Plaintiffs' Motion for Partial Summary Judgment

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS
TITLE 22. SOCIAL SECURITY
DIVISION 3. HEALTH CARE SERVICES
SUBDIVISION 1. CALIFORNIA MEDICAL ASSISTANCE PROGRAM
CHAPTER 3. HEALTH CARE SERVICES
ARTICLE 7. PAYMENT FOR SERVICES AND SUPPLIES

This database is current through 06/09/06, Register 2006, No. 23.

s 51513. Pharmaceutical Services and Prescribed Drugs.

(a) Definitions. The following definitions are applicable to Sections 51513, 51513.2, 51513.5, 51520.1, and 59998.

(1) Generic Drug means the chemical or generic name, as determined by the United States Adopted Names Council (USANC) and accepted by the Federal Food and Drug Administration (FDA), of those drug products having the same active ingredients.

(2) Generic Drug Type means the dosage form, strength, and package size, where applicable, of a specific generic drug. Legend Generic Drug Type means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription" or words of similar import.

(3) Drug Product means a brand or trade name of a generic drug type manufactured, packaged, or distributed by a specific pharmaceutical company which is the principal labeler.

(4) Medical Supply Type means the particular kind of a medical supply product.

(5) Medical Supply Product means a brand or trade name of a medical supply type manufactured, packaged, or distributed by a specific company which is the principal labeler.

(6) **Estimated Acquisition Cost** (EAC) for a medical supply product means the Average Wholesale **Price** or such other **price** as the Department determines to be the **price generally** and **currently paid** by providers for a standard package. EAC for a drug product means the Department's **best estimate** of the **price generally** and **currently paid** by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package. The EAC for a drug product shall be:

(A) The Direct **Price** as determined pursuant to section 51513.5; or

(B) The Average Wholesale **Price** minus 5 percent (AWP-5%) for all other drug products.

(7) Average Wholesale **Price** (AWP), excepting temporary updates as provided in subdivision (a)(13), means the **price** for a drug product or a medical supply product listed for a standard package in the Department's primary **price** reference source, or for products not listed in the Department's primary **price** reference source, the **price** listed for a standard package in the secondary **price** reference source; and, if not listed in the secondary **price** source, the principal labeler's catalogue. The selection of the primary **price** reference source and the secondary **price** reference source shall be based upon an evaluation of the various **price** reference sources available in relation to the following criteria:

(A) Accuracy and **currentness** of **prices**.

(B) Comprehensiveness of data base.

(C) Capability to meet the needs of the Department's fiscal intermediary.

The primary **price** reference source will be the **price** reference source that, in the judgment of the Director, **best** meets the criteria specified above. The secondary **price** reference source will be the **price** reference source that, in the judgment of the Director when evaluated against the criteria listed above, is inferior to the primary **price** reference source but superior to all others evaluated.

(8) A Standard Package means 100s, pints or pounds, if commercially available; or the commercially available size that is next above 100s, pints or pounds; or, in the case of larger quantities, that size which is closest to the quantity dispensed; or, in the case of conventional dispensing units, the unit dispensed; or, in those cases in which the only commercially available sizes are less than 100s, pints or pounds, the package closest to the amount dispensed. Where the

most frequently purchased size differs from the above limits, a standard package shall mean that package size determined by the Director to be the size most frequently purchased by providers, and designated with a "++" on the Medi-Cal List of Contract Drugs. The National Drug Code (NDC) of the Package from which the drug is dispensed shall be used when billing Medi-Cal. Payment for the drug dispensed is based on a standard package as defined in this subsection.

(9) Maximum Allowable Ingredient **Cost** (MAIC) means the **price** established by the Director for a generic drug type, and Maximum Allowable Product **Cost** (MAPC) means the **price** established by the Director for a medical supply type.

(10) Federal Allowable **Cost** (FAC) means the **price** established for a generic drug type by the United States Department of Health and Human Services in accordance with sections 447.331 and 447.332, Title 42, Code of Federal Regulations for which drug product(s) are available to pharmacies from a regional California drug wholesaler with AWP at or below such **price**.

(11) **Cost** of the Drug Product or Medical Supply Product, except in cases of prior authorization as provided in subsection (a)(14), means the lowest of the **Estimated Acquisition Cost** (EAC), the Federal Allowable **Cost** (FAC), or the Maximum Allowable Ingredient **Cost** (MAIC)/Maximum Allowable Product **Cost** (MAPC) for the Standard Package size. The EAC, the FAC and the MAIC/MAPC shall be updated by the Director no less often than every 60 days for medical supply products and no less often than every 30 days for drug products. In order to reflect the most **current price** information available, the Director may temporarily update the EAC, or the MAIC/MAPC, to reflect the **price** listed for a standard package in the principal labeler's catalog or catalog supplements, until the most recent change in **price** is reflected in the **price** listed in the Department's primary **price** reference source, or for products not listed in the Department's primary **price** reference source, the secondary **price** reference source.

(12) **Cost** of the drug product or medical supply product for which Prior Authorization has been granted in accordance with section 51003, for a drug product or medical supply product having a higher **cost** than the established FAC or MAIC/MAPC, means the EAC of the drug product or medical supply product authorized by the Medi-Cal consultant. Such prior authorization requests shall be made by the prescriber or pharmacist, and shall contain adequate information to justify the medical necessity for the higher cost drug product or medical supply product. For mail-in prior authorization requests, the justifying information shall be either handwritten and signed by the prescriber or pharmacist, or typewritten on the prescribers office letterhead or prescription blank and signed by the prescriber. Telephone prior authorization requests shall be transmitted exclusively by the prescriber or pharmacist.

(13) Principal Labeler means the specific supplier of a product under whose brand, trademark, trade name or other trade symbol a generic drug type or medical supply type is placed into its final commercially available package. The principal labeler does not include any person who affixes supplemental labeling to an existing commercially available package of a drug or medical supply.

(14) Final commercially available package means that original processed and labeled drug or medical supply package which requires no further processing or labeling to be lawfully sold to a provider of services.

(b) Payment for Legend Generic Drug Types.

(1) Payment for legend generic drug types dispensed by licensed pharmacists in compliance with Section 51313 shall consist of the cost of the legend generic drug type dispensed, plus a professional fee for services. Payments for legend generic drug types dispensed by a clinic with a special permit pursuant to Business and Professions Code, Section 4063, and provided in compliance with Section 51313 shall consist of the cost of the legend generic drug type dispensed.

(A) The price charged to the program shall not exceed that charged to the general public.

(B) The pharmacist or the clinic with a special permit, to the extent permitted by law, shall dispense the lowest cost drug product within the generic drug type that the pharmacy or clinic with a special permit has in stock which meets the medical needs of the beneficiary.

(2) Payment to a pharmacy for both the professional fee component and the ingredient cost component for legend generic drug types listed in Part 1 of the Medi-Cal List of Contract Drugs and preceded by "#" shall be limited to drugs dispensed in minimum quantities of 100 dosage units. Payment to a pharmacy for less than 100 dosage units for legend generic drug types listed in Part 1 of the Medi-Cal List of Contract Drugs and preceded by "#" shall be for the ingredient cost only. One hundred dosage units means 100 tablets or capsules. Exceptions to this requirement shall be:

(A) The initial prescription for the legend generic drug type for the beneficiary.

(B) Those prescriptions for which prior authorization is obtained from a Medi-Cal consultant.

(C) Those prescriptions for skilled nursing facility or intermediate care facility inpatients; however, such prescriptions shall be subject to the requirements of subparagraph (b)(3) of this section.

(3) Payment to a pharmacy for both the professional fee component and the ingredient cost component of claims for dispensing legend generic drug types listed in Part 1 of the Medi-Cal List of Contract Drugs and preceded by "+" shall be limited to a maximum of three such payments in any 75-day period when the same legend generic drug type is provided to the same beneficiary. Payment to a pharmacy for more than three such claims in any 75-day period shall be limited to the ingredient cost only. Exceptions to this requirement shall be:

(A) The initial prescription for the legend generic drug type for the beneficiary.

(B) Those prescriptions for which prior authorization is obtained from a Medi-Cal consultant.

(C) Any drug dispensed in a quantity of 180 or more tablets or capsules.

(4) Payment to a pharmacy for oral contraceptive legend generic drug types listed in Part 1 of the Medi-Cal List of Contract Drugs shall be limited to a minimum quantity of three cycles. Payment to a pharmacy for less than a quantity of three cycles shall be for the ingredient cost only. Exceptions to this requirement shall be:

(A) The initial prescription for the legend generic drug type for the beneficiary.

(B) Those prescriptions for which prior authorization is obtained from a Medi-Cal consultant.

(5) Payment to a pharmacy for both the professional fee component and the ingredient cost component for theophylline liquid or for liquid potassium supplement legend generic drug types listed in Part 1 of the Medi-Cal List of Contract Drugs shall be limited to a minimum quantity of 480 cc. Payment to a pharmacy for less than a quantity of 480 cc shall be for the ingredient cost only. Exceptions to this requirement shall be:

(A) The initial prescription for the legend generic drug type for the beneficiary.

(B) Those prescriptions for which prior authorization is obtained from a Medi-Cal consultant.

(c) Payment for Nonlegend Generic Drug Types Excluding Nonlegend Cough and Cold Drugs. Payment for nonlegend generic drug types provided in compliance with Section 51313 shall consist of the cost of the generic drug type dispensed plus 50 percent of cost, except that payments to clinics with special permits shall consist of the cost of the generic drug type dispensed. The price charged to the program shall not exceed that charged to the general public. The pharmacist or the clinic, to the extent permitted by law, shall dispense the lowest cost drug product within the generic drug type that the pharmacy or clinic has in stock which meets the medical needs of the beneficiary.

(d) Payment for Nonlegend Cough and Cold Drug Products.

(1) Subject to the requirements of paragraph 2, payment for nonlegend cough and cold drug products listed in Part 3 of the Medi-Cal List of Contract Drugs provided in compliance with Sections 51313 and 51313.3 shall be **cost** of the drug

product supplied plus 50 percent of **cost**, except that payment to clinics with special permits shall be only the **cost** of the drug product. The **price** charged to the program shall not exceed that charged to the **general** public ("shelf **price**"). The pharmacist or the clinic, to the extent permitted by law, shall dispense the lowest **cost** drug product within the classification specified in Part 3 of the Medi-Cal List of Contract Drugs, that the pharmacy or clinic has in stock which meets the medical needs of the beneficiary.

(2) Nonlegend cough and cold drug products listed in Part 3 of the Medi-Cal List of Contract Drugs are payable when supplied to beneficiaries in manufacturers' original trade packages, and in the package sizes specified in Part 3 of the Medi-Cal List of Contract Drugs; an equivalent to these original trade package sizes is also payable, if the drug product supplied is that of the same manufacturer who produces the original trade package sizes specified. Additional fee for professional prescription labeling with individual directions for use is not payable. A record of the drug product supplied may be kept separate from the prescription file. This record shall contain all the information required on the pharmacy claim form used as the payment claim to the program for the drug product supplied.

(e) Fee for Service. The maximum professional fee component for services shall be $4.05. Additional charges for extemporaneously compounded prescriptions shall be allowed according to the following schedule:

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Capsules and Papers
6-36....................................
.......  $1.98
37-100..................................
........  3.95
Ointments
    up to 180
Gm......................................
1.64
    180 Gm and
over.................................
3.29
Suppositories
    up to
24......................................
..  3.29
    24 and
over....................................
.  5.76
Sterile Eye Preparations
All.....................................
........  2.04
Nose and Ear Preparations
All.....................................
........  0.81
Emulsions
    up to
240cc...................................
..  0.81
    240cc and
over..................................
1.64
 Liquids other than simple pouring or
reconstituting
All.....................................
........  0.99
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(f) Fee for Partial Prescription Refills. The fee for a partial prescription refilled in accordance with Business and Professions Code section 4229.5 or Health and Safety Code section 11201 shall be the fee amount allowed for refill of the full prescription quantity multiplied by the percent of the full prescription quantity finally refilled. The total of the fees for partial refills of such prescription shall not exceed the fee for the same prescription when refilled as a routine service. The claim for the completed service, signed by the provider, shall reflect such fee determination.

(g) Drugs Administered for Chronic Outpatient Hemodialysis. Drugs administered for chronic outpatient hemodialysis in renal dialysis centers and community hemodialysis units are payable only when included in the all inclusive rate set forth in section 51509.2.

<General Materials (GM) - References, Annotations, or Tables>

Note: Authority cited: Sections 10725, 14105, 14105.7 and 14124.5, Welfare and Institutions Code; and Section 208, Health and Safety Code. Reference: Section 4211, Business and Professions Code; Sections 14105, 14105.7, 14105.35, 14132, 14133 and 14133.1, Welfare and Institutions Code; Fiscal Year 1989-90 Budget Act (Chapter 93, Statutes of 1989); 42 U.S.C. Section 1396a(a)(30)(A); and 42 C.F.R. Sections 447.301, 447.302, 447.304, 447.331, 447.332, 447.333 and 447.334.

HISTORY

1. Amendment of subsection (d) filed 8-1-84 as an emergency; effective upon filing (Register 84, No. 31). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 11-29-84. For prior history, see Registers 83, No. 34; and 82, No. 49.

2. Amendment of subsections (a), (a)(10), (a)(12) and (a)(13) filed 10-3-84; effective thirtieth day thereafter (Register 84, No. 40).

3. Certificate of Compliance as to 8-1-84 order transmitted to OAL 11-27-84 and filed 12-27-84 (Register 84, No. 52).

4. Amendment of subsection (d) filed 1-31-85 as an emergency; designated effective 2-1-85 (Register 85, No. 5). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-1-85.

5. Certificate of Compliance transmitted to OAL 5-23-85 and filed 6-24-85 (Register 85, No. 26).

6. Amendment of subsection (d) filed 8-1-85 as an emergency; effective upon filing (Register 85, No. 32). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 11-29-85.

7. Relettering of subsections (d)-(f) to subsections (e)-(g) and new subsection (d) filed 9-16-85 as an emergency; effective upon filing (Register 85, No. 39). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 1-14-86.

8. Certificate of Compliance as to 8-1-85 order transmitted to OAL 11-20-85 and filed 12-27-85 (Register 85, No. 52).

9. Certificate of Compliance as to 9-16-85 order transmitted to OAL 1-2-86 and filed 2-3-86 (Register 86, No. 7).

10. Amendment of subsections (a)(9), (a)(13), (b)(4) and (b)(5) filed 7-28-86; designated effective 9-1-86 (Register 86, No. 31).

11. Amendment of subsection (a)(13) filed 6-10-87; operative 7-10-87 (Register 87, No. 25).

12. Amendment of subsections (a)(12)-(14) filed 10-27-87 as an emergency;
operative 10-29-87 (Register 87, No. 44). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 2-26-88.

13. Certificate of Compliance transmitted to OAL 2-24-88 and filed 3-25-88 (Register 88, No. 14).

14. Amendment of subsection (a)(8) filed 9-14-89 as an emergency; operative 10-16-89 (Register 89, No. 38). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 2-13-90.

15. Amendment of subsection (a)(8) refiled 2-13-90 as an emergency; operative 2-13-90 (Register 90, No. 9). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-
13-90.

16. Certificate of Compliance as to 2-13-90 order transmitted to OAL 6-8-90 and
disapproved 7-9-90 (Register 90, No. 34).

17. Amendment of subsection (a)(8) refiled 7-12-90 as an emergency; operative 7-12-90 (Register 90, No. 34). A Certificate of Compliance must be transmitted to OAL by 11-9-90 or emergency language will be repealed by operation of law on the following day.

18. Amendment of subsection (a)(8) refiled 11-16-90 as an emergency; operative
11-16-90 (Register 90, No. 52). A Certificate of Compliance must be transmitted to OAL by 3-18-91 or emergency language will be repealed by operation of law on the following day.

19. Amendment of subsections (a) and (e), and Note filed 3-22-91; operative 4-
21-91 (Register 91, No. 15).

20. Certificate of Compliance as to 11-16-90 order including amendment of NOTE
transmitted to OAL 3-12-91 and filed 4-11-91 (Register 91, No. 17).

21. Amendment of subsections (a), (b), (c) and (d) and repealer of subsections (e) and (f) filed 5-22-91 as an emergency pursuant to Statutes of 1990, chapter
456, section 36, p. 1658-1659; operative 5-22-91 (Register 91, No. 27). A Certificate of Compliance must be transmitted to OAL by 9-19-91 or emergency language will be repealed by operation of law on the following day.

22. Amendment of subsections (a), (b), (c) and (d) refiled 9-19-91 as an emergency; operative 9-20-91 (Register 92, No. 4). A Certificate of Compliance must be transmitted to OAL 1-20-92 or emergency language will be repealed by operation of law on the fol-

lowing day.

23. Amendment of subsections (a), (b), (c) and (d) refiled 1-23-92 as an emergency; operative 1-17-92 (Register 92, No. 25). A Certificate of Compliance must be transmitted to OAL 5-22-92 or emergency language will be repealed by operation of law on the following day.

24. Certificate of Compliance as to 1-23-92 order including amendment of subsections (a)(2), (a)(10)-(11), (a)(13)-(14) and (d)(2) and Note transmitted
to OAL 5-22-92 and filed 7-6-92 (Register 92, No. 28).

25. Amendment of subsections (b)(1), (b)(1)(B), (c) and (d)(1) and Note filed 1-6-94; operative 2-7-94 (Register 94, No. 1).

26. Amendment of subsections (a)(1)-(3), (a)(5), (a)(10)-(12), (b)-(b)(1), (b)(1)(B)-(b)(2)(A), (b)(3)-(b)(3)(A), (b)(4)-(b)(4)(A), (b)(5)-(b)(5)(A) and (c), repealer of subsections (a)(6)-(7) and (a)(17) filed 1-9-95; operative 3-1-95 (Register 95, No. 2).

27. Change without regulatory effect renumbering subsections filed 4-26-95 pursuant to section 100, title 1, California Code of Regulations (Register 95, No. 17).

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